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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,126	12/22/2003	Mami L. Allen	MCP-5019	8463
27777 7590 04/18/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/743,126	Applicant(s) ALLEN ET AL.	
	Examiner Jagadishwar R. Samala	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/22/03; 08/19/05 & 01/20/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 24-34 in the reply filed on February 09, 2007 is acknowledged. The traversal is on the ground(s) that examining a method of custom sweetening a pharmaceutical dosage form and a customization agent and a kit comprising said pharmaceutical dosage form and a customization agent does not present the examiner with a search burden. This is not found persuasive because claims 1-23 and 24-34 differ in scope as indicated by their distinct modes of operation. As such, claims 1-23 are withdrawn for further consideration pursuant to 37 CFR 1.142 (b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claims. Applicant's timely traversed the restriction (election) requirement in the reply filed on February 09, 2007. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 24-26, 29, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandyopadhyay et al. (US 2002/0143038 A1).

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Bandyopadhyay discloses a packaging kit comprising a first container containing a solid lyophilized epothilone analog and second container containing a sufficient quantity of an equal mixture of suitable nonionic surfactant and anhydrous ethanol to effect solution thereof. Bandyopadhyay also discloses instructions for combining said dosage forms (see claim 1).

It is noted that the intended use recited in the claims are considered, but the claims are properly included in this rejection because a recitation of the intended use of claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

3. Claims 24-26 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wenke et al (US 5,628,799).

Wenke discloses a kit comprising a first container containing a dopa species solution containing the direct dye or, optionally, the primary intermediate and/or coupler, and a second container containing the oxidant solution. The buffer may be individually packaged in a third container in an amount sufficient to provide a suspension of dopa species (see column 12, lines 12-22). And also, Wenke further discloses a kit comprising two or more containers of reactant-containing solutions, and with printed instructions to mix the solutions in order to form the hair dye composition (see column 11, lines 65+).

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Thus, the claims are readily envisaged by the teachings of the cited reference and the claims are properly included in the rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandyopadhyay et al. (US 2002/0143038 A1) or Wenke et al (US 5,628,799) or Mylari (US 2001/0056095 A1) in view of Weinstein et al. (US 5,695,930).

Mylari discloses a kit comprising a container for containing the separate compositions such as a divided bottle or a divided foil packet. And also the kit comprises instructions for the administration of the pharmaceutical components. Bandyopadhyay or Wenke or Mylari meets the claim limitations as described above but fails to include a third container comprising an additional quantity of same or different

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dosage form therein. However, a kit comprising a third container containing standard reagents is well known in the art as shown by Weinstein.

Weinstein discloses a kit comprising first container containing a solid human immunodeficiency virus antigens, a second container containing a secondary antibody specific for mammalian salivary antibodies and a third compartment containing standard reagents necessary for the reporter molecule to produce a signal.

At the time of the invention, it would have been obvious to one skilled in the art to modify the kit and to incorporate a third container in the kit disclosed by Bandyopadhyay or Wenke or Mylari. One motivation is provided by Weinstein in that the kit comprising a third container with standard reagents provides for an improved method of packaging a drug delivery kit. Additionally the kit form is particularly advantageous when the separate components are preferably administered in different dosage forms at different dosage intervals or when titration of the individual components of the combination is desired by the prescribing physician. One skilled in the art would recognize that the enhanced properties of kits designed or intended for administering several dosage forms of the same or two separate pharmaceutical compositions is highly desirable. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teaching of Weinstein to the invention advanced by Bandyopadhyay or Wenke or Mylari.

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Conclusion


1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER